

nOPV Group

Ratified Terms of Reference [Approved: September 3, 2021]

Purpose

The nOPV Group is a time-limited group that will manage and coordinate GPEI's activities to enable a rapid and effective roll out of nOPV2 as the tool of choice for responding to cVDPV2 outbreaks. As the development of nOPV candidates for other serotypes of polio advances, the nOPV group will facilitate programmatic alignment and decision-making related to their future deployment on behalf of GPEI.

Responsibilities

The core nOPV group will be responsible for the following areas of work:

- Policy: Support SAGE endorsement for moving out of the initial use period including support to the Global Advisory Committee on Vaccine Safety. Engage with regional and country policy-making bodies to provide technical guidance and support.
- Lead coordination, discussion, advancement and/or resolution of cross-cutting issues across all sub-groups and areas of work related to nOPV use.
- Coordinate ongoing review and updating of nOPV2 technical guidance after the initial use phase including safety and surveillance, decision-making and advocacy, communications, cold chain logistics and vaccine management, and laboratory and diagnostics work.
- Provide technical guidance to outbreak response group and regional/country support teams as requested throughout the period of use under EUL.
- Facilitate programmatic alignment and decision-making related to nOPVs 1&3 as that work advances
- Work with the GCG nOPV communications liaisons to document and develop case studies of the initial use experience.
- Support the VSG if needed to ensure the availability of nOPV2 in sufficient quantities and establish risk mitigation strategies as needed.

The following subgroups and liaison functions of the nOPV group will lead work across a range of areas, through the implementation of identified priorities.

1. **Research and Data Analysis:** Monitor progress on initiation and implementation of nOPV2 Phase 3 study and other studies including immunogenicity in naïve infants and concomitant administration with bOPV and escalate key issues or concerns and provide updates to the core nOPV Group. Provide guidance and feedback during planning of studies and registries required to fulfill EUL requirements, including pregnancy observational study, pregnancy registry and immunodeficiency registry. Support study sponsors / principal investigators in data interpretation and analysis from studies to contribute to review of nOPV2 safety. Members of this subgroup will oversee/coordinate field, observational and other studies, including seroprevalence survey and nOPV2 field effectiveness evaluation. This subgroup will receive update from study leads for all studies mentioned above and can provide guidance should issues arise during conduct of the studies. Working with other GPEI groups such as the Polio Research and Analytics Group, identify areas for disease modeling and provide technical input, as necessary. Identify whether additional studies are needed. This subgroup may provide review and feedback on study

protocols and publications at the request of the study leads and / or the vaccine manufacturer during the time that nOPV2 would be under EUL. The subgroup will also be responsible for ensuring communication with stakeholders externally, such as Bio Farma, to ensure as license holder they are aware of all clinical activities with nOPV2.

2. **Manufacturer Support:** Provide strategic input to address manufacturer-related issues that may arise. Facilitate preparation of data packages for remaining data from phase II clinical trials and data packages for eventual (2023) submission for nOPV2 full-licensing pre-qualification. As development of nOPVs 1&3 develop, provide manufacturers with regulatory support as needed.
3. **Genetic Characterization:** Support Bio Farma's fulfilment of its obligations under the EUL related to monitoring of the genetic stability of nOPV2. Collate nOPV2-related AFP and ES genetic sequencing data from CDC and NIBSC laboratories. Systematically and in a timely manner review the nOPV2 genetic sequencing data as well as nOPV2 virological data generated by all laboratories involved in the AFP and ES monitoring activities for nOPV2. In compliance with the EUL requirements, report monthly the results of the nOPV2 data review to the core nOPV group for reporting to GPEI. On an ad hoc basis, report any results that raise concerns to the nOPV group who will share with GPEI. Make recommendations to the nOPV group regarding continued safety of nOPV2 use. Support related to nOPVs 1&3 will be assessed once those products have developed further.
4. **Safety Coordination:** Work with stakeholders to support: (1) development of safety guidance for countries; (2) articulation of safety data inputs required from countries by the GACVS Sub-committee Secretariat; (3) support regions to ensure country readiness to collect and analyse safety data; (4) tracking of progress; and (5) sharing of data and analysis with Bio Farma; liaison with Bio Farma and WHO PQ for ongoing review and evaluation of nOPV2 use
5. **(Independent sub-group) Readiness Verification Team:** Ensure compliance with EUL commitments related to country readiness by coordinating with the Readiness Verification Team and ensure timely implementation of the readiness verification process
6. **(Time-limited group, sunset expected by end of Q3/2021): nOPV Initial Use Country Support:** During the initial use period, support regions and countries to use nOPV2. After the initial use period, transition country readiness and implementation support to the designated GPEI outbreak response team and Regional Offices (transition underway). Support will be provided for nOPVs 1&3 once their development has sufficiently progressed; no support is required in the short-term.
7. **(Time-limited role, sunset expected by end of Q1/2022): Liaison for Communications:** Until nOPV2 use is well established, the nOPV group will coordinate closely, through communication liaisons and directly, with the Global Communication Group (GCG) to support communication needs within regions and countries as they prepare to use nOPV2 and rollout the vaccine. After nOPV2 use is well established, the GCG will continue to provide communication guidance and input on nOPV2 publications and case studies. No support is needed for nOPVs 1&3 until that work has advanced.

Gender Perspective

Gender mainstreaming (the process of assessing implications for women and men of any planned action, in all areas and at all levels) is an integral dimension to the achievement of gender equality, which is considered a powerful determinant of health outcomes and a major factor in the movement towards polio eradication.

The nOPV group is responsible for supporting gender mainstreaming and the GPEI gender strategy within the group by:

- Dedicating time to develop and undertake activities to mainstream gender in their respective group, in conjunction with the Gender Mainstreaming Group (GMG), on an annual basis, and ensuring completion of activities (e.g., training via webinars, coaching, and/or mentoring).
- Leveraging technical support from the GMG, where feasible and applicable, throughout the course of activities (i.e., across program planning, design, implementation, monitoring, evaluation) to ensure that a gender equality lens is being applied.
- Being aware of GPEI's Gender Equality Strategy KPIs and implementing actions to help meet the expected results, leveraging support from the GMG, where needed.

Outputs

- Costed annual priorities, including the development of a roadmap and timelines
- Regular reports on progress to SC (standing item on SC agenda), POB, SAGE WG, SAGE and other global policy making groups, as requested or relevant
- Regular reports to Bio Farma and WHO PQ to support fulfillment of EUL requirements
- Minutes of calls, meetings and decisions
- Decision papers, as required, for discussion and approval at SC

Composition

Leadership

- The nOPV group shall be led by a Chair and Vice-Chair.
 - The SC will appoint the named parties for the roles of Chair and Vice-Chair after soliciting feedback from the nOPV group members, using coordination support from the SC Secretariat. It is recommended that the individuals nominated to these two roles do not come from the same organization.
 - The term for each role is 12 months, with the option for rotation (preferred) or renewal at the discretion of the SC.
- Each GPEI partner nominate one person as their core nOPV group member, along with an alternate who will also function as a member of the core group.
 - The nOPV group will establish appropriate sub-groups or identify nOPV specific liaisons to oversee each of the critical areas of work. In areas where sub-groups have been established, key links will be reinforced with existing GPEI groups, to ensure alignment and avoid duplication. Sub-group leads and liaisons will join core group calls, to ensure the core group has the necessary functional experience to fulfil its duties. Sub-group membership may include individuals who are not part of the working group or part of GPEI (i.e., regional colleagues, PATH, regulators, etc.).

Membership Expectations

In general, individual members of the nOPV group have the following responsibilities:

- Be familiar with the charge and work of the nOPV group.
- Have pertinent expertise (e.g., epidemiology, business) and/or represent the perspective of an agency or stakeholder group.
- Attend 70% of all meetings (and for the entire duration of the meetings).
 - A committee member who misses two consecutive meetings, when the member has not made a case for exception to the Chair, may be replaced.

- If replacement of a member is required, the Chair will flag the issue with the pertinent agency and make the request.
- Be actively engaged at all meetings and provide relevant and focused comments (e.g., ensure that you have read circulated pre-read materials and have developed perspective on the topic area prior to attending the meeting).
- Dedicate time to participating in and/or leading work/activities, outside of planned meeting times.
 - The specific amount of time is to be estimated by the Chair and Vice-Chair and discussed with individual members at the start of the year but is generally expected to range from 10 to 20 hours/month.
- Demonstrate flexibility in unanimity building discussions and take different perspectives into account.
- Relay discussions and updates on work undertaken, back to the member's respective agency, to ensure coordinated efforts across GPEI and the agency (e.g., to minimize duplicative activities).
- Efforts will be made to guarantee gender balanced representation of members (ideally 50% women and 50% men) and to alternate among different level positions (to avoid appointing only junior positions).
- All core members will be offered additional gender training opportunities according to their needs/competencies.

For groups that have distinguished Core Members vs. Non-Core Members in their respective TOR:

- For Core Members, the above applies.
- For Non-Core Members (i.e., Supplementary or Liaison Roles), the Chair determines the responsibilities.

For partner agencies that propose individual member names to serve on the nOPV group, the above must be taken into consideration. The recommendation is to discuss capacity with the potential candidate, prior to a proposal to serve on the nOPV group.

Secretariat

- The Secretariat role shall be determined by the Chair.
- There shall be one individual designated as the primary contact for the Secretariat, regardless of how many individuals actively work to support the nOPV group in its activities.
- The Secretariat supports the nOPV group with the following, as needed:
 - Facilitating work in collaboration with the Chair and Vice-Chair;
 - Scheduling meetings;
 - Planning logistics;
 - Compiling agendas;
 - Distributing meeting materials (pre-reads and post-discussion), including meeting minutes;
 - Tracking action items and coordinating on progress to closure of action items;
 - Scheduling and preparing progress reports, in conjunction with the Chair and Vice-Chair;
 - Coordinating with other groups; and
 - Maintaining responsibility for relevant documents (e.g., knowledge management / information management /online portal for sharing materials).
- The secretariat will also include a technical coordinator, who will directly support the core working group members, under the guidance of the Chair and Vice-Chair.

Accountability

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- The nOPV group will report to the SC via the EMU.
- The nOPV group will maintain close links with other GPEI groups to ensure coordination of activities and avoid duplication.

Limits of authority

By delegation from the SC, the nOPV group is authorized to:

- Appoint the leads/co-leads of its sub-groups.
- Approve sub-group ToRs and annual workplans.
- Develop budgets and funding requests for nOPV2-related activities.
- Approve resource allocation for workplans within approved budget, with the authority to reallocate funding across WG budget lines staying within the approved funding envelope.

Decision Making

- Unanimity is the ideal for all decisions made by the nOPV group and should be pursued wherever possible.
- If unanimity cannot be reached, a majority vote will be the deciding factor. Each agency stipulated in the TOR with voting rights (e.g., core member) gets one vote.
- If a majority vote cannot be reached, the Chair of nOPV group will escalate to the EMU. The EMU will determine the appropriate next step on the escalation path (e.g., mediation attempt, escalation to SC).
- For decisions with significant strategic impact, if a member dissents with a particular decision, escalation may be made to the EMU. The EMU decides whether a further review is required by the SC, on a case-by-case basis; if escalated to SC, their decision will be final.

Rhythm of Business

Meetings

- The nOPV group will meet monthly by teleconference (TC) through 2021, with each meeting 90 min in length. Frequency of calls will be evaluated after this. Ad hoc TCs will be arranged by the Secretariat as required.
- In-person meetings will be arranged by the Secretariat at least once a year if safe to do so
- Sub-groups will set up their own operating rhythm but are expected to hold a TC at least once per month.

Duration

- The nOPV group will function through the EUL period for nOPV2 (PQ is anticipated during 2023). After that time, its role and continuation will be assessed by the SC.

TOR Ratification

- By February 28, 2022, this TOR is to be reviewed by the Chair and Vice-Chair; this timing equates to ~6 months after initial ratification by the SC.
- Post-February 28, 2022, this TOR is to be reviewed by the Chair and Vice-Chair, on an annual basis, at minimum.
- After reviews by the Chair and Vice-Chair, any proposed amendments to the TOR must be submitted to the EMU, for approval by the SC. Amendments can be submitted on an as needed basis.